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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/681,750

10/07/2003

Philipp Lang

2960/113

8141

75059 7590 11/25/2008
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EXAMINER

MONTANO, MELISSA ANN

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

11/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/681,750	Applicant(s) LANG ET AL.	
	Examiner MELISSA MONTANO	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) 22-39, 57-65 and 67-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 40-56 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/25/2004, 3/29/2004, 11/9/2007, 12/3/2007,</u> | 6) ☐ Other: _____ |
| <u>1/14/2008</u> | |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, claims 1-79 and 90-95, and Species 2, claims 1-21, 40-56, and 66 in the reply filed on 12/11/2007 is acknowledged.
2. Claims 22-39, 57-65, and 67-95 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/11/2007. Duplicate claim 59 is canceled.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 6, 7, 9, 10, and 52-56 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 6 and 7 recite the limitation "offset value". This term does not appear to be adequately described in applicant's disclosure. The examiner suggests that applicant provide further explanation of what is meant by the "offset value" claimed.
6. Claim 9 recites the limitation "the material" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 52 recites the limitation "the margin" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 53 recites the limitation "the superior margin" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 54 recites the limitation "the

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inferior margin" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 55 and 56 recite the limitation "the device" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-3, 6-11, 15-21, 40-50, 52-53, 55-56, and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2003/0055501 A1 to Fell et al. (Fell).

Fell teaches an implantable knee prosthesis intended to fill in the space that results from cartilage loss on both the femoral condyle and tibial plateau (abstract and page 4, paragraph 0057). The implant has a superior surface (106) and an inferior surface (104) that match the shape of the femoral and tibial articular surfaces, respectively (page 2, paragraph 0025). Fell also teaches that the implant effectively replaces worn articular material and may be thicker in places of cartilage wear (page 2 and 3, paragraphs 0017 and 0054). The implant, taught by Fell, can be made of soft, compliant material designed to assume the function of the natural meniscus which it replaces, such as steel, thermoplastic polymers, or biologically active components (page 5, paragraph 0072). The examiner asserts that the use of biologically active components would necessarily result in an ingrowth of bone/tissue after implantation and would therefore meet the limitation of changing configuration after insertion into the

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joint. The implant is offered in multiple thicknesses (the examiner asserts that this constitutes a selection from a library of implants) and insertion is done via a 3cm to 5cm incision (page 2, paragraph 0025). Further, Fell teaches that in some patients, it may be desirable to offset the femoral surface of the implant laterally with respect to the tibial geometry to put the femur back in a more normal alignment (page 3, paragraph 0056, lines 4-7). The examiner asserts that Fell's contemplation of an offset femoral surface would necessarily constitute an offset value selected to adjust for axis malalignment, as claimed by applicant. Further still, Fell teaches the thickness along the periphery of the implant being greater than the thickness along the center of the implant and a peripheral edge (412) that extends at an incline between the superior surface (406) and the inferior surface (404), as shown in Fig. 4c, resulting in the superior surface (406) extending over the notch (408) of the inferior surface (406). The examiner asserts that this would necessarily constitute the superior margin extending further laterally than the inferior margin, as claimed by applicant. The examiner also asserts that since the peripheral edge extends at an incline between the superior surface and the inferior surface, there would necessarily be a positive, negative, or null slope present. Fell teaches that the edges (margins) of the implant are rounded (page 6, paragraph 0079, line 1) and that a patient can achieve approximately 120 degrees of flexion (page 7, paragraph 0096). The examiner asserts that 120 degrees of flexion would necessarily constitute a restored range of motion of the joint between 80-99.9%, as claimed by applicant.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fell in view of US Patent No. 6,206,927 B1 to Fell et al. (Fell '927).

Fell teaches the implant according to claim 1 that is offered in multiple thicknesses of a cartilage defect in a patient (page 2, paragraph 0025, lines 19-20). However, Fell does not explicitly teach the claimed thickness percentages.

Fell '927 teaches a meniscal prosthetic device suitable for implantation into the cavity between a femoral condyle and corresponding tibial plateau (abstract). Fell '927 also teaches that the shape of the meniscal device may be tailored to the individual and provides a range of central thickness between 0.010-0.20 inches and a range of peripheral thickness up to 0.40 inches (col. 6, lines 30-44).

It has been held that "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." See MPEP 2144.05, Section II, *in re Peterson*. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the thickness of the implant taught by Fell, in order to tailor the device to the individual, as taught by Fell '927.

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4. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fell in view of US Patent No. 6,203,576 B1 to Afriat et al. (Afriat).

Fell teaches the implant according to claim 1. However, Fell does not teach a plurality of structures for attachment.

Afriat teaches a complete knee joint prosthesis including an intermediate plate (3) that has a central projecting rib (30), for the purpose of constituting a means of lateral retention of the femoral element (1) in relation to the intermediate plate (3) (col. 5, lines 50-53). The intermediate plate also has a cavity (35) on its lower face, for the purpose of allowing multidirectional movement of the intermediate plate (3) in relation to the tibial element (2) (col. 5, lines 53-55).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the implant of Fell to include a plurality of structures for attachment, in order to constitute a means of lateral retention with the femoral element and to allow multidirectional movement with the tibial element, as taught by Afriat.

5. Claims 51 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fell in view of US Patent No. 4,344,193 to Kenny (Kenny).

Fell teaches the implant according to claim 1. However, Fell does not teach an implant having a central portion greater in thickness than a portion of its periphery or an inferior margin that extends further than the superior margin.

Kenny teaches a meniscus prosthetic device for a human knee joint having prominences (15, 16) that are noticeably raised above the general surface of the device more so in the central portion than the periphery (fig. 2), and therefore have a greater

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thickness in the central portion than the periphery, for the purpose of securing the prosthetic device in position (col. 3, lines 3-4). Kenny also teaches that varying sizes of inner and outer condyles should be taken into account when sizing the device for placement in a human knee (col. 2, lines 41-47). The examiner asserts that it is well-known that individual patients require different sizing and placement of implants and therefore the limitation of the inferior margin extending further than the superior margin would necessarily be met by the implant taught by Kenny if it was a requirement for proper fitting in the patient receiving the implant.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the implant of Fell to include a greater thickness in the central portion of the implant in order to secure the implant in position, as taught by Kenny. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the implant of Fell to include an inferior margin that extends further than the superior margin in order to meet individual fitting requirements of the patient.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-14, 18, 20, 43-44, 46-49, and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 16, and 19-25 of copending Application No. 10/752,438. Although the conflicting claims are not identical, they are not patentably distinct from each other because an implant suitable for a condyle of a femur would necessarily be suitable for a knee joint.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-6, 8-21, 40-51, 55-56, and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7, 10-23, 44-53, and 60-69 of copending Application No. 10/681,749. Although the conflicting claims are not identical, they are not patentably distinct from each other because a superior and inferior surface would necessarily constitute a superior and inferior surface. Similarly, a femoral and tibial surface would necessarily constitute a first and second articular surface of a joint.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference US Patent No. 5,522,900 to Hollister discloses a prosthetic joint dimensioned so that members of the joint remain in contact and effectively duplicate a normal anatomical range of motion.

The reference US Patent No. 5,681,354 to Eckhoff discloses an asymmetric distal femoral prosthetic component for a knee prosthesis having a medial and lateral condyle with varying sulcus angles that can be selected to closely approximate the sulcus angle observed in a patient's normal knee.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA MONTANO whose telephone number is (571)270-5785. The examiner can normally be reached on Monday-Friday 8:00AM-5:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738